

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: John B. Harley, Judith Ann James, and Kenneth M. Kaufman

Serial No.: Divisional of 09/718,693 Art Unit: Not Yet Assigned

Filed: August 22, 2003 Examiner: Not Yet Assigned

For: *ASSAYS AND THERAPIES FOR LATENT VIRAL INFECTION*

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicants submit an Information Disclosure Statement, including fifteen (15) pages of Form PTO-1449. All of the documents cited below were cited by or submitted to the Patent Office in Application Serial No. 09/718,693, filed November 22, 2000, to which the present application claims priority. Pursuant to 37 C.F.R. §1.98(d), Applicants are not enclosing copies of these publications. Copies will be provided upon request, however.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) prior to a first Office Action on the merits. It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 50-1868.

U.S.S.N.: Divisional of 09/718,693
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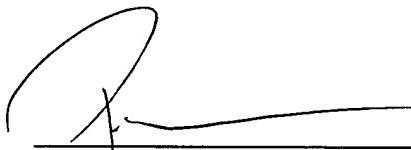
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Remarks

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicants are of the opinion that their claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,



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Dated: August 22, 2003

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Filing Date	August 22, 2003		
First Named Inventor	John B. Harley		
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Filing Date	August 22, 2003		
First Named Inventor	John B. Harley		
Group Art Unit			
Examiner Name			
Sheet 2 of 15	Attorney Docket Number	OMRF 177 DIV	

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Sheet	3	of	15
			Attorney Docket Number
			OMRF 177 DIV

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		BROWNING, et al., <i>J. Immunol.</i> 143: 1859-1867 (1989).
		CALDERWOOD, et al., "Nucleotide sequence of the Shiga-like toxin genes of <i>Escherichia coli</i> ," <i>Proc. Natl. Acad. Sci. USA</i> 84: 4364-4368 (1987).
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		CHEN, et al., <i>J. Biol. Chem.</i> 266: 18237-18243 (1991).
		COLOMBATTI, et al., <i>J. Biol. Chem.</i> 261: 3030-3035 (1986).
		DALLDORF, et al., "The Lymphomas of Brazilian Children," <i>J. Am. Med. Assn.</i> 208: 1365-8 (1969).
		DEACON, et al., "Detection of Epstein-Barr Virus Antigens and DNA in Major and Minor Salivary Glands Using Immunocytochemistry and Polymerase Chain Reaction: Possible Relationship with Sjogren's Syndrome," <i>J. Pathol.</i> 163: 351-360 (1991).
		DEACON, et al., "Frequency of EBV DNA Detection in Sjogren's Syndrome," <i>Am J. Med.</i> 92: 453-454 (1992).
		DEBRUS, et al., "Varicella-zoster virus gene 63 encodes an immediate-early protein that is abundantly expressed during latency," <i>J. Virol.</i> 69: 3240-3245 (1995).
		DEDRICK, et al., <i>Cancer Treat. Rep.</i> 62: 1-11 (1978).

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Sheet	4	of	15	Application Number	Divisional of 09/718,693
				Filing Date	August 22, 2003
				First Named Inventor	John B. Harley
				Group Art Unit	
				Examiner Name	
				Attorney Docket Number	OMRF 177 DIV

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		DELEERS, et al., <i>FEBS Lett.</i> 160: 82-86 (1983).	
		DIENER, et al., "Specific Immunosuppression by Immunotoxins Containing Daunomycin," <i>Science</i> 231(4734): 148-150 (1986).	
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		FERREL, et al., <i>J. Clin. Invest.</i> 67: 681-687 (1981).	
		FINERTY, et al., "Immunization of Cottontop Tamarins and Rabbits with a Candidate Vaccine Against the Epstein-Barr Virus Based on the Major Viral Envelope Glycoprotein gp340 and Alum," <i>Vaccine</i> 12: 1180-1184 (1994).	
		FINERTY, et al., "Protective Immunization Against Epstein-Barr Virus-Induced Disease in Cottontop Tamarins Using the Virus Envelope glycoprotein gp340 Produced from a Bovine Papillomavirus Expression Vector," <i>J. Gen. Virol.</i> 73: 449-453 (1992).	

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		FOX, "Sjogren's Syndrome," <i>Current Opin. Rheum.</i> 7: 409-416 (1995).	
		FOX, et al., "Detection of Epstein-Barr Virus-Associated Antigens and DNA in Salivary Gland Biopsies from Patients with Sjogren's Syndrome," <i>J. Immunol.</i> 137: 3162-3168 (1986).	
		FOX, et al., "Potential Role of Epstein-Barr Virus in Sjogren's Syndrome and Rheumatoid Arthritis," <i>J. Rheumatol.</i> 19: 18-24 (1992).	
		GLASSY, et al., <i>J. Immunol. Methods</i> 81: 115 (1985).	
		GOODRICH, et al., <i>Ann. Intern. Med.</i> 118:173-178 (1993).	
		GRAY, et al., "Cloning, nucleotide sequence, and expression in <i>Escherichia coli</i> of the exotoxin A structural gene of <i>Pseudomonas aeruginosa</i> ," <i>Proc. Natl. Acad. Sci. USA</i> 81: 2645-2649 (1984).	
		GREENWOOD, et al., <i>Biochem. J.</i> 89: 114-123 (1963).	
		GRIFFITHS, et al., <i>Cancer Res.</i> 51: 4594-4602 (1991).	
		GU, et al., "First EBV Vaccine Trial in Humans Using Recombinant Vaccinia Virus Expressing the Major Membrane Antigen," <i>Dev. Biol. Stand.</i> 84: 171-177 (1995).	
		GUTIERREZ, et al., "Switching Viral Latency to Viral Lysis: A Novel Therapeutic Approach for Epstein-Barr Virus-Associated Neoplasia," <i>Cancer Res.</i> 56: 969-972 (1996).	

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		HAAHR, et al., "A Putative New Retrovirus Associated with Multiple Sclerosis and the Possible Involvement of Epstein-Barr Virus in This Disease," <i>Ann. N. Y. Acad. Sci.</i> 724: 148-156 (1996).
		HALPERN, et al., <i>J. Nucl. Med.</i> 29: 1688-1696 (1988).
		HARLEY & JAMES, "Epstein-Barr virus infection may be an environmental risk factor for systemic lupus erythematosus in children and teenagers," <i>Arthr. Rheum.</i> 42(8): 1782-1783 (1999).
		HESLOP, et al., "Long-Term Restoration of Immunity Against Epstein-Barr Virus Infection by Adoptive Transfer of Gene-Modified Virus-Specific T Lymphocytes," <i>Nature Med.</i> 2: 551-555 (1996).
		HISKEY, <i>Peptides</i> 3: 137 (1981).
		HO, <i>Cytomegalovirus, biology and infection: current topics in infectious disease</i> Plenum Press: New York, pp. 105-118 (1982).
		HOCH, et al., "Channels formed by botulinum, tetanus, and diphtheria toxins in planar lipid bilayers: relevance to translocation of proteins across membranes," <i>Proc. Natl. Acad. Sci. USA</i> 82: 1692-1696 (1985).
		HWANG, et al., <i>Cell</i> 48: 129-136 (1987).
		INOUE, et al., "Analysis of Antibody Titers to Epstein-Barr Virus Nuclear Antigens in Sera of Patients with Sjogren's Syndrome and with Rheumatoid Arthritis," <i>J. Infect. Dis.</i> 164: 22-28 (1991).
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		JAMES & HARLEY, "Linear Epitope Mapping of an Sm B/B' Polypeptide," <i>J. Immunol.</i> 148: 2074-2079 (1992).	
		JAMES, et al., "Immunoglobulin Epitope Spreading and Autoimmune Disease After Peptide Immunization: Sm B/B'-derived PPPGMRPP and PPPGIRGP Induce Spliceosome Autoimmunity," <i>J. Exp. Med.</i> 181: 453-461 (1995).	
		JAMES, et al., "An increased prevalence of Epstein-Barr virus infection in young patients suggests a possible etiology for systemic lupus erythematosus," <i>J. Clin. Invest.</i> 100: 3019-26 (1997).	
		JAMES, et al., <i>Arthr. Rheum.</i> 41: S308 (1998).	
		JI, <i>Meth. Enzymol.</i> 91: 580-609 (1983).	
		KAHAN, et al., <i>Arthr. Rheum.</i> 28: 961-70 (1985).	
		KARAMERIS, et al., "Detection of the Epstein Barr Viral Genome by an <i>in situ</i> Hybridization Method in Salivary Gland Biopsies from Patients with Secondary Sjogren's Syndrome," <i>Clin. Exp. Rheum.</i> 10: 327-332 (1992).	
		KHANNA, et al., "Peptide transporter (TAP-1 and TAP-2)-independent endogenous processing of Epstein-Barr virus (EBV) latent membrane protein 2A: Implications for cytotoxic T-lymphocyte control of EBV-associated malignancies," <i>J Virology</i> 70(8): 5357-5362 (1996).	
		KIMURA, et al., <i>Clin. Exp. Immunol.</i> 103: 192-298 (1996).	
		KITAGAWA, et al., "Detection of Antibodies to the Epstein-Barr Virus Nuclear Antigens in the Sera from Patients with Systemic Lupus Erythematosus," <i>Immunol. Lett.</i> 17:249-252 (1988).	

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		KOHLER & MILSTEIN, <i>Nature</i> 256: 495-497 (1975).	
		KOHLER & MILSTEIN, <i>Eur. J. Immunol.</i> 6: 511-519 (1976).	
		KOIDE, et al., "Spontaneous establishment of an Epstein-Barr virus-infected fibroblast line from the synovial tissue of a rheumatoid arthritis patient," <i>J. Virol.</i> 71: 2478-2481 (1997).	
		KONDO & YAMANISHI, 24 th International Herpesvirus Workshop, July 17-23 (Mass. Inst. Tech.) Abst. 1.016 (1999).	
		KONDO, et al., "Human cytomegalovirus latent gene expression in granulocyte-macrophage progenitors in culture and in seropositive individuals," <i>Proc. Natl. Acad. Sci. USA</i> 93: 11137-1142 (1996).	
		KOYAMA, et al., <i>Chem. Abstr.</i> 120: 217-262 (1994).	
		KRAUSE & STRAUSS, <i>Infect. Dis. Clin. N.A.</i> 13: 61-81 (1999).	
		LARSEN, et al., "Epstein-Barr Nuclear Antigen and Viral Capsid Antigen Antibody Titers in Multiple Sclerosis," <i>Neurology</i> 35:435-438 (1985).	
		LAZAROVITS, et al., "Anti-B Cell Antibodies for the Treatment of Monoclonal Epstein-Barr Virus-Induced Lymphoproliferative Syndrome After Multivisceral Transplantation," <i>Clin. Invest. Med.</i> 17:621-625 (1994).	
		LENNETTE, et al., "Antibodies to LMP2A/2B in EBV-carrying malignancies," <i>Eur. J. Cancer</i> 31(11): 1875-1878 (1995).	

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		LEVITSKAYA, "Inhibition of Antigen Processing by the Internal Repeat Region of the Epstein-Barr Virus Nuclear Antigen-1," <i>Nature</i> 375:685-688 (1995).
		LONGNECKER & KIEFF, "A second Epstein-Barr virus membrane protein (LMP2) is expressed in latent infection and colocalizes with LMP1," <i>J. Virol.</i> 64: 2319-2326 (1990).
		MASSEN, et al., <i>Eur. J. Biochem.</i> 134: 32 (1983).
		MAHALINGAM, et al., "Expression of protein encoded by Varicella-Zoster virus open reading frame 63 in latently infected human ganglionic neurons," <i>Proc. Nat'l. Acad. Sci. USA</i> 93: 2122-2124 (1996).
		MAITLAND, "Frequency of EBV-DNA Detection in Sjogren's Syndrome," <i>Am. J. Med.</i> 96:97 (1994).
		MARIETTE, et al., "Detection of Epstein-Barr Virus DNA by <i>in Situ</i> Hybridization and Polymerase Chain Reaction in Patients with Sjogren's Syndrome," <i>Am. J. Med.</i> 90:286-294 (1991).
		MARKMAN, <i>Semin. Oncol.</i> 18: 248-254 (1991).
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		MEARES, et al., <i>Anal. Biochem.</i> 142: 68-78 (1984).
		MEIGNER, et al., <i>J. Infect. Dis.</i> 162: 313-321 (1990).

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		MERRIFIELD, J. Am. Chem. Soc. 85: 2149 (1964).
		MIYASHITA, et al., "Identification of the site of Epstein-Barr virus persistence in vivo as a resting B cell," J. Virol. 71: 4882-4891 (1997).
		MOCARSKI, "Cytomegaloviruses and their replication" in <i>Fields Virology</i> , 3 rd ed. (Fields, et al. eds.) Lippincott-Raven pp. 2447-2480 (1996).
		MORGAN, "Epstein-Barr Virus Vaccines," Vaccine 10:563-571 (1992).
		MORGAN, et al., "Validation of a First-Generation Epstein-Barr Virus Vaccine Preparation Suitable for Human Use," J. Med. Virol. 29:74-78 (1989).
		MORSHED, et al., "Increased Expression of Epstein-Barr Virus in Primary Biliary Cirrhosis Patients," Gastroenterol. Jpn. 27(6):751-758 (1992).
		MUJOO, et al., <i>Oncogene</i> 12:1617-1623 (1996).
		MUSAINI, et al., <i>Ann. Rheum. Dis.</i> 46: 837-42 (1987).
		MYERS, et al., <i>J. Immunol. Meth.</i> 121(1): 129-142 (1989).
		NAKABAYASHI, et al., <i>Rheumatol. Int.</i> 5: 61-7 (1985).

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	Divisional of 09/718,693
Filing Date	August 22, 2003		
First Named Inventor	John B. Harley		
Group Art Unit			
Examiner Name			
Sheet	11	of	15
		Attorney Docket Number	OMRF 177 DIV

OTHER ART -- NON PATENT LITERATURE DOCUMENTS		
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published
		NEWKIRK, et al., "Detection of Cytomegalovirus, Epstein-Barr Virus and Herpes Virus-6 in Patients with Rheumatoid Arthritis With or Without Sjogren's Syndrome," <i>Br. J. Rheum.</i> 33:317-322 (1994).
		NG, et al., <i>Lancet</i> 1(8166): 447-9 (1980).
		Ol, et al., "Chimeric antibodies," <i>BioTechniques</i> 4(3): 214 (1986).
		PALLESEN, et al., "Expression of Epstein-Barr Virus Latent Gene Products in Tumor Cells of Hodgkin's Disease," <i>Lancet</i> 337(8737): 320-322 (1991).
		PFLUGFELDER, et al., "Amplification of Epstein-Barr Virus Genomic Sequences in Blood Cells, Lacrimal Glands, and Tears from Primary Sjogren's Syndrome Patients," <i>Ophthalmology</i> 97:976-984 (1990).
		PFLUGFELDER, et al., "Epstein-Barr Virus and the Lacrimal Gland Pathology of Sjogren's Syndrome," <i>Am. J. Pathol.</i> 143:49-64 (1993).
		PLOTKIN, et al., <i>J. Infect. Dis.</i> 159: 860-865 (1989).
		PLOTKIN, et al., <i>Infect. Immun.</i> 12: 521-527 (1975).
		PLOTKIN, et al., <i>Rev. Infect. Dis.</i> 12: 827-838 (1990).
		QUADRI, et al., <i>Nucl. Med. Biol.</i> 20: 559-570 (1993).

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	Divisional 109/718,693
Sheet	12	of	15
		Attorney Docket Number	OMRF 177 DIV

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		REUSSER, et al., <i>J. Infect. Dis.</i> 166: 473-479 (1992).
		RICKINSON & KIEFF, "Epstein-Barr virus" in <i>Fields Virology</i> . Lippincott-Raven, pp. 2397-2446 (1996).
		RODWELL, et al., "Site-specific covalent modification of monoclonal antibodies: <i>in vitro</i> and <i>in vivo</i> evaluations," <i>Proc. Natl. Acad. Sci.</i> 83: 2632-2636 (1986).
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		SABBATINI, et al., "Autoantibodies from Patients with Systemic Lupus Erythematosus Bind a Shared Sequence of AnD and Epstein-Barr Virus-Encoded Nuclear Antigen EBNA 1," <i>Eur. J. Immunol.</i> 23:1146-1152 (1993).
		SADZOT-DELVAUX & BENTIER, 24 th International Herpesvirus Workshop July 17-23 (Mass. Inst. Tech.) Abst. 9.009 (1999).
		SADZOT-DELVAUX, et al., <i>J. Immunol.</i> 159: 2802 (1997).
		SALACINSKI, et al., <i>Anal. Biochem.</i> 117: 136-146 (1981).
		SCHMIDT, et al., "Proc. Natl. Acad. Sci. USA 88(21): 9478-9482 (1991).

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Filing Date	August 22, 2003		
First Named Inventor	John B. Harley		
Group Art Unit			
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		SCOTET, et al., <i>J. Exp. Med.</i> 184: 1771-1780 (1996).	
		SCOTET, et al., "Frequent enrichment for CD8 T cells reactive against common herpes viruses in chronic inflammatory lesions: towards a reassessment of the physiopathological significance of T cell clonal expansions found in autoimmune inflammatory processes," <i>Eur J. Immunol.</i> 29: 973-985 (1999).	
		SCULLEY, et al., "Reactions of Sera from Patients with Rheumatoid Arthritis, Systemic Lupus Erythematosus and Infectious Mononucleosis to Epstein-Barr Virus-Induced Polypeptides," <i>J. Gen. Virol.</i> 67:2253-2258 (1986).	
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		STEPLEWSKI, et al., "Isolation and characterization of anti-monosialoganglioside monoclonal antibody 19-9 class-switch variants," <i>Proc. Natl. Acad. Sci., USA</i> 82: 8653-8657 (1985).	
		STRAUS, et al., <i>Ann. Int. Med.</i> 108: 221 (1988).	
		SUMAYA, et al., "Increased Prevalence and Titer of Epstein-Barr Virus Antibodies in Patients with Multiple Sclerosis," <i>Ann. Neurol.</i> 17:371-377 (1985).	

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Filing Date	August 22, 2003		
First Named Inventor	John B. Harley		
Group Art Unit			
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Sheet	14	of	15
		Attorney Docket Number	OMRF 177 DIV

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		SUN, et al., <i>Hybridoma</i> 5(Supp1): S17 (1986).
		SUNDBERG, et al., <i>Nature</i> 250: 587-588 (1974).
		TAKEI, et al., <i>Int. Immunol.</i> 9: 739-743 (1997).
		TAN, <i>Rev. Inf. Dis.</i> 1: 997-1006 (1979).
		TATEISHI, et al., "Spontaneous Production of Epstein-Barr Virus by B Lymphoblastoid Cell Lines Obtained from Patients with Sjogren's Syndrome," <i>Arthritis Rheum.</i> 36:827-835 (1993).
		THORLEY-LAWSON, et al., "Epstein-Barr virus and the B cell: that's all it takes," <i>Trends in Microbiology</i> 4(5): 204-208 (1996).
		TODA, et al., "Sjogren's syndrome (SS) and Epstein-Barr virus (EBV) reactivation," In <i>Lacrimal Gland, Tear Film, and Dry Eye Syndrome</i> , (D.A. Sullivan, ed.) pp. 647-650 (Plenum Press, New York 1994).
		TSAI, et al., "Detection of Epstein-Barr Virus and Cytomegalovirus Genome in White Blood Cells from Patients with Juvenile Rheumatoid Arthritis and Childhood Systemic Lupus Erythematosus," <i>Int. Arch. Allergy Immunol.</i> 106:235-240 (1995).
		VENABLES, et al., "Persistence of Epstein-Barr Virus in Salivary Gland Biopsies from Healthy Individuals and Patients with Sjogren's Syndrome," <i>Clin. Exp. Immunol.</i> 75:359-364 (1989).
		VENABLES, et al., "The Response to Epstein-Barr Virus Infection in Sjogren's Syndrome," <i>J. Autoimmunity</i> 2:439-448 (1989).

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		VENABLES, et al., <i>Arthr. Rheum.</i> 24: 1459-1468 (1981).	
		VRISENDORP, et al., "Radioimmunoglobulin therapy" in <i>High Dose Cancer Therapy</i> (Armitage, et al. eds) Williams & Wilkins: Baltimore, pp. 84-123 (1992).	
		WAGSTAFF, et al., "Aciclovir - A Reappraisal of its Antiviral Activity, Pharmacokinetic Properties and Therapeutic Efficacy," <i>Drugs</i> 47:153-205 (1994).	
		WANG, et al., <i>Radiat. Res.</i> 141: 292-302 (1995).	
		WARNER & CARP, "Multiple Sclerosis Etiology - an Epstein-Barr Virus Hypothesis," <i>Med. Hypotheses</i> 25:93-97 (1988).	
		WATSON, et al., "Certain Properties Make Substances Antigenic," in <i>Molecular Biology of the Gene</i> , Fourth Edition, page 836, paragraph 3, (The Benjamin/Cummings Publishing Company, Menlo Park, 1987).	
		WHITLEY, "Herpes Simplex viruses" in <i>Field's Virology</i> Lippincott-Raven, pp. 2297-2330 (1996).	

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